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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,039	07/18/2003	Subhashis Banerjee	117813-18801	1401

87501 7590 09/17/2009

McCarter & English, LLP / Abbott Laboratories Ltd.
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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
09/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,039	BANERJEE ET AL.	
	Examiner	Art Unit	
	DAVID J. BLANCHARD	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,12,18,22,23 and 26-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,12,18,22,23 and 26-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/8/09; 8/6/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 2, 5-11, 13-17, 19-21 and 24-25 have been cancelled.

2. Claims 1, 3-4, 12, 18, 22-23 and 26-56 are pending and under consideration to the extent that the spoondyloarthropathy is psoriatic arthritis, i.e., applicants' elected species.

Information Disclosure Statement

3. The Information Disclosure Statement (IDS) filed 08 July 2009 and 06 August 2009 have been considered by the Examiner. A signed and initialed copy of each IDS is included with the instant Office Action.

Objections/Rejections Maintained and New Grounds of Rejections

4. The objection to the specification as disclosing various non-provisional US Application numbers whose status has changed and require updating is maintained.

Applicant's remarks filed 5/26/2009 are acknowledged, however, in view that USSNs 10/163,657 and 10/622,932 are pending and may require updating during the pendency of the instant application, the objection is being maintained for convenience.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The rejection of claims 1, 3-4, 12, 18, 22-23 and 26-56 under 35 U.S.C. 103(a) as being unpatentable over Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001, cited on PTO-892 mailed 9/24/07) in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980, cited on PTO-892 mailed 9/24/07) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C64 filed 5/13/08) is maintained.

The response filed 5/26/2009 argues that the examiner is improperly relying upon an obvious to try standard in the instant rejection, citing MPEP 2143(E) for support. Applicant states that dosage amounts alone or in combination with a dosing schedule provide an infinite number of possible combinations for treatment. There exists a limitless number of dosage amounts that can be used in any given treatment, as there also exists a limitless dosing schedule in terms of how frequently an agent may be delivered. Accordingly, the combination of dose amounts and frequency is equally infinite, and does not represent a finite number of identified, predictable potential solutions to the allegedly recognized need or problem. Applicants' arguments have been fully considered but are not found persuasive. In contrast to applicants' arguments and consistent with MPEP 2143(E), the teachings of Ogilvie et al provide an effective

therapy for treating psoriatic arthritis using an anti-TNFα antibody, thereby establishing a recognized problem or need in the art and a predictable potential solution to the recognized need or problem and one of ordinary skill in the art could have pursued the known subcutaneous biweekly administration of the known fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et al at 20 mg, 40 mg and 80 mg for the treatment of psoriatic arthritis, since the teachings of Keystone et al indicate that the administered D2E7 antibody was well tolerated and therapeutically effective, particularly at 40 mg every other week. Again, "[A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. Thus, in view of the teachings of Keystone et al, the examiner does not agree that there is an infinite number of dosage amounts and frequency.

Applicant also argues that one of ordinary skill in the art would not combine the teachings of Keystone et al with Ogilvie et al to arrive at the claimed invention because Ogilvie et al teaches the successful treatment of psoriatic arthritis. Applicant states that one of ordinary skill in the art would not have been led to the subcutaneous administration of a fixed dose (i.e., the same dosage throughout the course of treatment) based on the successful teachings of Ogilvie et al regarding infusion based administration of infliximab using a weight-based dosing scheme. Even assuming *arguendo* that one of ordinary skill in the art would be motivated to substitute a human anti-TNFα antibody, or antigen-binding fragment thereof, for infliximab for treating psoriatic arthritis based on the teachings of Ogilvie et al (which Applicants deny), the examiner has not supported why one of ordinary skill in the art would have changed the regimen described in Ogilvie et al, given the successful treatment. Applicants' arguments have been fully considered but are not found persuasive. The idea that one of ordinary skill in the art would not modify the teachings of Ogilvie et al et al since Ogilvie et al teaches the successful treatment of psoriatic arthritis makes little sense since the prior art teaches that because chimeric and humanized antibodies still retain some of murine sequence, they still may elicit an unwanted immune reaction in human patients. Thus one of ordinary skill in the art would have been motivated to use the fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et

al (identical to the claimed antibodies) in order to avoid any unwanted immune reaction in human psoriasis patients due to the presence of murine sequences in the chimeric anti-TNFα antibody (Infliximab) of Ogilvie et al.

Further, since one of ordinary skill in the art would have been led to the fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et al as, it makes little sense that one of ordinary skill in the art would follow the dosing regimen for infliximab when using the fully human anti-TNFα antibody D2E7, particularly in view that the subcutaneous biweekly subcutaneous administration of the fully human anti-TNFα antibody D2E7 at 20 mg, 40 mg and 80 mg was known to be well tolerated and therapeutically effective, particularly at 40 mg every other week. It would make more sense to follow a known dosing regimen for the antibody actually used in the therapy, rather than follow the dosing regimen for a different antibody and which might be limited by unwanted immune reaction in human patients.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

7. The rejection of claims 1, 3-4, 12, 18, 22-23 and 26-56 under 35 U.S.C. 103(a) as being unpatentable over Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) in view of Salfeld et al [b] (U.S. Patent 6,509,015 B1, 2/9/1996, IDS reference A2 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C64 filed 5/13/08) is maintained.

The applied reference (Salfeld et al [b]) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was

derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The response filed 5/26/2009 argues as above and the examiner's remarks above apply here as well and are incorporated herein by reference. It is noted that the instant rejection differs only in the use of Salfeld et al [b], however, Salfeld et al [a] and [b] are equivalent teachings.

Therefore, as discussed supra the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. The rejection of claims 1, 3-4, 12, 18, 22-23 and 26-56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 36-39 and 69 of U.S. Patent No. 6,509,015 B1 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) and Keystone

et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C64 filed 5/13/08) is maintained.

The response filed 5/26/2009 argues as above, i.e., the claims invention is not derived from a finite number of possible combinations described in the art and is not an optimization of a known process and there is no motivation to combine the cited references or modify the primary reference given the successful teachings of Ogilvie et al . Applicants' arguments have been fully considered but are not found persuasive for the reasons set forth above and incorporated herein by reference, and in view that no terminal disclaimer has been filed.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,509,015 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

10. The provisional rejection of claims 1, 3-4, 12, 18, 22-23 and 26-56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-5, 8-11, 14, 38-39, 49-50, 52-53 and 55-57 of copending Application No. 11/435,844 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) and Smith et al (Arthritis

Rheum. 23(8):961-962, August 1980) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C64 filed 5/13/08) is maintained.

The response filed 5/26/2009 notes that the rejection is provisional in nature and submits that this rejection will be further addressed when the claims are otherwise in condition for allowance. Applicants' remarks are acknowledged, however, the claims are not currently in condition for allowance and no terminal disclaimer has been filed and as such, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/435,844, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

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11. The provisional rejection of claims 1, 3-4, 12, 18, 22-23 and 26-56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 19, 56, 66, 77 and 87 of copending Application No. 11/233,252 in view of Ogilvie et al (British Journal of

Dermatology, 144(3):587-589, March 2001) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C64 filed 5/13/08) is maintained.

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12. The provisional rejection of claims 1, 3-4, 12, 18, 22-23 and 26-56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 1, 4-10, 16-21, 78-79, 81, 84, 86-88, 95, 97-98 and 100-104 of copending Application No. 10/163,657 in view of

Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) is maintained.

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A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643